

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the following remarks. By this amendment, claim 20 is cancelled. This amendment is not to be construed as acquiescence to any rejection and is made without prejudice to prosecution of any subject matter modified by the amendment in a related divisional, continuation, or continuation-in-part application.

Rejection Under 35 U.S.C. § 112

Claims 21 and 23 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly being directed to subject matter not adequately described in the instant specification. More specifically, the Action asserts that claims drawn to polypeptide variants having at least 90% identity to SEQ ID NO:809 and claims drawn to fragments comprising at least 10 amino acid residues of SEQ ID NO:809 lack written description in the instant specification sufficient to support the entire claimed genus.

Applicants respectfully traverse this rejection and submit that the instant application clearly conveys to the skilled artisan that Applicants had possession of the claimed invention at the time of filing.

As an initial matter, Applicants submit that the instant specification provides adequate written description to support the genus of polypeptides with at least 90% sequence identity with SEQ ID NO:809. Under the Examination Guidelines set forth by the Patent and Trademark Office, the written description requirement for a claimed genus may be satisfied by the description of a representative number of species or the disclosure of relevant, identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶1, "Written Description" Requirement, 66 Fed. Reg. 1099, at 1106. Applicants submit that the instant application meets both criteria.

First, Applicants submit that the instant specification describes a representative number of claimed species by providing the sequence of polypeptides of SEQ ID NO:809 as well as describing sequences with at least 90% identity to these polypeptides. Applicants note that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species the genus embraces. *Id.* Applicants submit that by providing a reference sequence and the percent identity limitation, the specification adequately describes a representative number of claimed variants, since one skilled in the art would readily identify a claimed sequence and recognize that Applicants were in possession of said sequence at the time the application was filed.

In addition, Applicants submit that the instant specification discloses sufficient identifying characteristics for L552S-related polypeptides that are common to the genus of polypeptides with at least 90% identity to a polypeptide of SEQ ID NO:809, since it provides both a reference sequence and percent identity limitations. Polypeptides of this genus clearly share the structural characteristic of at least 90% identity with a polypeptide sequence of SEQ ID NO:809. Moreover, Applicants submit that the instant application satisfies both the possession and notice functions of the written description requirement, since one of skill in the art would clearly be able to recognize and identify a claimed polypeptide based upon the instant specification and would also understand that Applicants had possession of said polypeptides at the time the application was filed.

Applicants further submit that the instant specification provides adequate written description to support claims directed to polypeptides comprising at least 10 consecutive amino acid residues of SEQ ID NO:809. Applicants submit that by providing the polypeptide sequence of SEQ ID NO:809, the specification clearly provides written description for fragments of the polypeptide sequence. Applicants submit that the skilled artisan would readily appreciate that Applicants were in possession of fragments of the polypeptides they identified, including polypeptides of SEQ ID NO:809 and claimed variants thereof. As described in the instant specification, fragments and immunogenic portions of polypeptides of SEQ ID NO:809 fall within the scope of Applicants' invention (*e.g.*, page 75, line 24, to page 77, line 15). Applicants further submit that fragments and immunogenic portions may generally be identified using well

known techniques, as described in the specification beginning on page 75, lines 28. In addition, the instant specification clearly describes the identification of such immunogenic fragments, *e.g.*, in Example 27, thus identifying specific immunogenic fragments and confirming that such fragments are identifiable by the skilled artisan.

Applicants also note that claim 25 is drawn to polypeptides comprising specific fragments of SEQ ID NO:809 identified in the instant specification as being immunogenic. Accordingly, Applicants submit that the written description requirement is clearly met for claim 25, since the sequence of such immunogenic fragments is specifically provided and recited in the claim.

Further still, Applicants submit that the tumor-associated expression profile identified by Applicants for polypeptides of SEQ ID NO:809 offers yet another important identifying characteristic from which the skilled individual would conclude that Applicants were in possession of the genus of polypeptides comprising at least a 10 amino acid portion of the polypeptide of SEQ ID NO:809 and the genus of polypeptides having at least 90% identity to the polypeptide of SEQ ID NO:809 at the time this application was filed.

The Examiner has focused his arguments regarding the alleged lack of written description for claimed L552S polypeptide fragments and variants on the intrinsic functional properties of the full length L552S polypeptide, asserting that Applicants have not demonstrated that the claimed fragments and variants possess the functional characteristics of the full length polypeptide. However, Applicants counter that this line of argument lacks credence in the context of the present invention, since the function of the L552S polypeptide is irrelevant for a variety of uses associated with the discovery that L552S polypeptides are overexpressed in lung cancer. One skilled in the art would readily understand that L552S polypeptides possess a variety of utilities, including, for example, both diagnostic and therapeutic uses, and that many of these utilities rely upon the tumor specificity of polypeptides of SEQ ID NO:809, a property only first identified by Applicants instant disclosure. Furthermore, one skilled in the art would recognize that these uses do not necessarily require a polypeptide with the entire sequence of a full length L552S polypeptide or the exact sequence as SEQ ID NO:809. Polypeptide fragments and variants may be used, for example, to generate antibodies against L552S polypeptides, and

such antibodies would be useful in the detection of cancer in the context of Applicants' disclosure, despite the fact that the variant sequence used to make the antibody was not the exact entirety of a polypeptide of SEQ ID NO:809. In addition, polypeptide fragments and variants of L552S may be used to detect antibodies to L552S, for example, in a lung tumor patient. Furthermore, the skilled artisan would expect that such variants and fragments, to the extent they are related to SEQ ID NO:809 and share epitopes with the L552S polypeptide of SEQ ID NO:809, were indeed in the possession of Applicants at the time of filing. In this regard, Applicants submit that L552S polypeptide fragments and variants would indeed be viewed by the skilled artisan as being useful, for example, in the detection of lung cancer, and being in possession of Applicants, based on their sequence identity to SEQ ID NO:809, based on the tumor specificity identified for SEQ ID NO:809, and further based on the clear understanding and expectation on the part of the skilled artisan that fragments of the L552S polypeptides of SEQ ID NO:809 are clearly useful in the context of Applicants' disclosure. Applicants thus submit that to accept the Action's position that Applicants were only in possession of polypeptides consisting of the single species of SEQ ID NO:809 would inappropriately exclude an entire class of polypeptides related to SEQ ID NO:809 that the skilled individual would appreciate were in Applicants' possession at the time of filing. This understanding and expectation on the part of the skilled artisan is submitted to be soundly based upon fundamental scientific principles.

In light of these remarks, Applicants submit that the instant application satisfies the written description of the claimed invention and respectfully request that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 101

Claim 20 stands rejected under 35 U.S.C. § 101, as allegedly claiming the same invention as claim 1 of U.S. Patent No. 6,630,574.

Without acquiescence to this basis and solely to expedite prosecution of the instant application, Applicants have canceled claim 20 by the present amendment, thereby obviating this basis of rejection. Withdrawal of this basis of rejection is respectfully requested.

Rejection for Nonstatutory Double Patenting

Claims 21-25 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 and 2 of U.S. Patent No. 6,630,574.

Applicants respectfully traverse this basis of rejection and submit that claims 21-25 are patentably distinct from the invention claimed in the '574 patent. Specifically, Applicants submit that the presently claimed invention, drawn to polypeptide variants and fragments comprising at least 10 amino acid residues of SEQ ID NO:809, would not be obvious to the skilled artisan over claims to the polypeptide of SEQ ID NO:809 or a fragment comprising 20 amino acids thereof. Clearly, the scope of the presently claimed subject matter is substantially different than that claimed in the '574 patent, since it encompasses both variants and smaller fragments (*i.e.*, at least 10 amino acids) of SEQ ID NO:809.

Nonetheless, to expedite prosecution of the instant application, Applicants submit herewith a terminal disclaimer directed to the '574 patent. Accordingly, Applicants respectfully request that this basis of rejection be withdrawn.

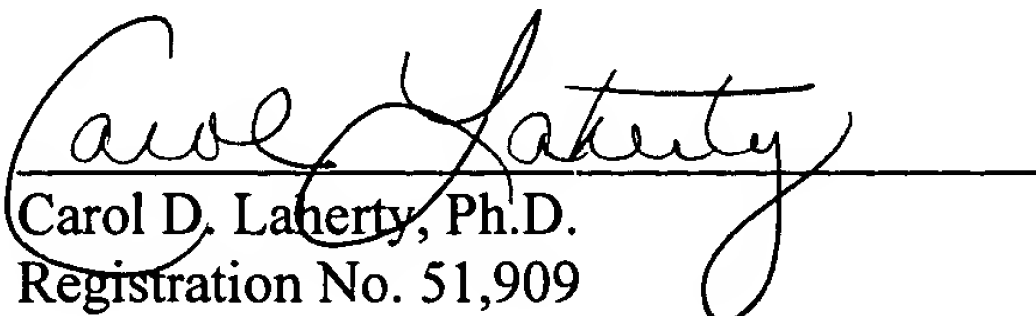
The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Application No. 09/902,941
Reply to Office Action dated June 29, 2004

Applicants respectfully submit that all of the claims remaining in the application are clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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